UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

LISA DAVIS,

Plaintiffs,

vs. Civil Action No.: _____

C.R. BARD, INC., a New Jersey corporation, and **BARD PERIPHERAL VASCULAR, INC.,** (a subsidiary and/or division of defendant C.R. BARD, INC.) an Arizona corporation,

Defendants.

C O M P L A I N T

NOW COMES the plaintiff, LISA DAVIS , and for her Complaint against the Defendants, C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC., a subsidiary corporation and/or division of C.R. BARD, INC., allege as follows:

THE PARTIES

1. Plaintiff, LISA DAVIS is a citizen and resident of the State of Michigan.

2. The defendant, C.R. BARD, INC., is a New Jersey corporation, with its principal place of business at 730 Central Avenue, Murray Hill, New Jersey, and conducts business throughout the United States including in the State of Michigan. At all times relevant hereto, defendant, C.R. BARD, INC., was or has been engaged in business in Michigan, and has conducted substantial business activity in North Carolina. Defendant has also carried on solicitations or service activities in the State of North Carolina.

3. The defendant, BARD PERIPHERAL VASCULAR, INC., a wholly owned

subsidiary and/or division of C.R. BARD, INC., with its principal place of business at 1625 West 3rd Street, Tempe, Arizona, conducts business throughout the United States including in the State of North Carolina. At all times relevant hereto, defendant, C.R. BARD, INC., was or has been engaged in business in North Carolina, and has conducted substantial business activity in North Carolina. Defendant has also carried on solicitations or service activities in the State of North Carolina.

STATEMENT OF VENUE AND JURISDICTION

4. Jurisdiction is proper in this Court under 28 U.S.C. § 1332(a)(1) because the plaintiffs and the defendants are citizens of different states, and the amount in controversy exceeds $75,000, excluding interest and costs.

5. Venue is proper in this Court under 28 U.S.C. § 1391, as a substantial part of the events or omissions giving rise to the claim occurred within this judicial district. Surgical placement, as well as attempted removal, of LISA DAVIS' G2™ Filter System was performed in Detroit, Michigan at Detroit Receiving Hospital and Henry Ford Bi-County Hospital said facilities being within this judicial district.

GENERAL BACKGROUND ALLEGATIONS

6. On or about June 20, 2008, LISA DAVIS sustained injuries when a medical device that had been previously implanted in her body (in July 2006) failed. This medical device is called an "inferior vena cava filter" or "IVC filter" and is discussed in more detail *infra*.

7. In June 2008, LISA DAVIS experienced heart palpitations, shortness of breath and vertigo. She presented to Detroit Medical Center as a result of her symptoms. Her

condition was diagnosed as arrhythmia and incidental findings of a metallic wire in the patient's right ventricle.

8. Ms. Davis was advised at that time that in order to remove the fractured filter wire from the right pulmonary artery she would have to undergo open heart surgery. At the present time Lisa Davis has declined to have open heart surgery. She was placed on metoprolol to assist with her heart arrhthymia as a result of the fractured filter. She is presently on life time anticoagulation therapy.

9. This action is filed within the applicable limitations period under Michigan law.

IVC FILTERS GENERALLY

10. The IVC filter at issue in this case bears the trademark name "G2" filter or "G2 Filter System". The G2 Filter System (hereafter "G2" or "G2 Filter") was manufactured, marketed, and sold by defendants, C.R. Bard, Inc. and/ or Bard Peripheral Vascular, Inc., from September 2005 until the present. The defendants continue to manufacture and sell the G2 throughout the United States of America and abroad.

11. IVC filters first came on the medical market decades ago. Over the years, several different medical device manufacturers have introduced several different designs of IVC filters.

12. An IVC filter is a device that is designed to filter or "catch" blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either permanently or temporarily, in the human body, more specifically, within the inferior vena cava.

13. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in

the legs and pelvis, through the vena cava and into the lungs. Often times, these thrombi develop in the deep leg veins. These thrombi are called "deep vein thrombosis (i) or 'DVT'". Once thrombi reach the lungs, they are considered "pulmonary emboli" or "PE". Pulmonary emboli present grave risks to human health. They can, and often do, result in death.

14. Certain people are at increased risk for the development of DVT or PE. For instance, someone who undergoes knee or hip joint replacement surgery is at risk for developing DVT/PE. Obese patients are also at increased risk for DVT/PE. So too are people who have vascular diseases or whom have experienced previous strokes. A number of other conditions predispose people to develop DVT/ PE.

15. Those people at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolitic events.

16. As stated in this Complaint, IVC filters have been on the market for decades. The first IVC filter was introduced in the late 1960's. Since then, the market has been supplemented with all types and designs of filters offered by many different manufacturers.

17. Over the years, a concern developed within the medical community (and was shared by IVC filter manufacturers) that an IVC filter should be designed and manufactured so that it is able to be retrieved from the human body. Ultimately, retrievable IVC filter designs were offered in the market. However, these IVC filter designs were not intended to remain within the human body for indeterminate periods of time. In other words, the initial designs of

retrievable IVC filters were intended to remain implanted for a finite period of time. The Recovery™ Filter System[1] (discussed in more detail *infra*) was introduced to the market in late 2002 or 2003 as an IVC filter that was able to be retrieved after an indeterminate time of placement within the human body.

THE G2™ FILTER

18. The G2 Filter is a medical device constructed of a nickel–titanium alloy (also called "Nitinol") designed to filter blood clots (thrombi) from the human circulatory system. Nitinol material is unique. Nitinol is actually an acronym that stands for **Ni**ckel **Ti**tanium **N**aval **O**rdnance **L**aboratory. Nitinol was developed by Navy scientists in 1962 as a material to be used in ordnance. Nitinol is also unique as it possesses "shape memory." That is, Nitinol will change shape according to change in temperature, and then, retake its prior shape after returning to its initial temperature. This quality makes Nitinol appealing for use in certain medical devices, including IVC filters.

19. The design of the G2 Filter finds its roots in a predecessor device, also designed, manufactured and sold by the defendants. The predecessor device was called the Recovery™ Filter system (hereafter "Recover" or "Recovery Filter").

20. As stated *supra*, the Recovery™ Filter System was indeed the predecessor/ predicate device for the G2 Filter. Soon after its introduction to the market, reports were made that portions of the device were fracturing and migrating to the anatomy and vital organs of the patients in whom it was implanted. These reports continued to surface and were made to healthcare providers, the F.D.A., and to the defendants. In fact, as early as 2003, the defendants

[1] The Recovery™ Filter System is the predecessor device to the G2 Filter.

were made aware that the Recovery™ Filter System was flawed and was causing injury and death to patients who had the filter implanted in their bodies.

21. The Recovery™ Filter System was plagued with manufacturing and design defects which caused the Recovery™ to experience a significant rate of fracture and migration of the device. Studies performed by members of the medical and scientific communities established that the Recovery™ Filter had a 21% to 31.7% rate of fracture.

22. The failure of the Recovery™ Filter System, as aforesaid, was attributable, in part, to the fact that the Recovery™ Filter System was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.[2]

23. Sometime after 2003, the defendants made a decision to introduce a substitute vena cava filter for Bard Peripheral Vascular's Recovery filter. This substitute vena cava filter was meant to replace the Recovery™ Filter System. It was to be called the "G2 Filter". G2 stands for "second generation".

24. In 2005, the defendants submitted an application to the F.D.A. for introduction of the G2™ Filter to the global market. The application was submitted under Section 510(k) of the United States Food, Drug and Cosmetic Act ("Act") of 1976 (21 U.S.C. 321 *et seq*). Under Section 510(k), a medical device manufacturer may represent that the device which is offered for approval is "substantially similar" to a "predicate device". With regard to the G2 Filter, the defendants represented to the F.D.A. that it was substantially similar to the Recovery™ Filter

[2]The Recovery™ Filter System was plagued with manufacturing defects, namely lack of preparation of the exterior surface of the device so as to eliminate gouges in the Nitinol struts of the device. These gouges caused or contributed to cause the Recovery™ Filter System to fail/fracture. The G2 Filter continues to have manufacturing defects in the form of "draw marks" on the exterior of the device.

System (the predicate device).

25. The defendants first received approval from the F.D.A. to market the G2 Filter as a permanent placement vena cava filter. That is, the G2 was not initially approved for retrievable use. The defendants began selling the G2 in September 2005. Later, in 2008, the G2™ Filter was approved by the F.D.A. as a retrievable (optional) IVC filter.

A COMPARISON OF THE RECOVERY™ FILTER SYSTEM AND THE G2™ FILTER SYSTEM

26. The Recovery™ Filter and the G2 Filter bear a strong resemblance in a number of respects. First, they look strikingly similar in appearance and have the same design for filtration. That is, the G2 Filter has six upper struts used for device positioning and filtering, and, six lower struts used for anchoring and filtering- just like the Recovery™ Filter.

27. In addition, the G2 Filter is made of the same alloy material as the Recovery™ Filter System. They both were manufactured of Nitinol, discussed *supra*.

28. Like the Recovery™ Filter, the G2 Filter is inserted *via* catheter that is guided by a physician (typically an interventional radiologist) through a blood vessel into the inferior vena cava. Both filters are designed to be retrieved in a somewhat similar fashion.

29. Following endovascular placement of the G2 Filter, a physician typically uses imaging studies (such as x-rays, "vena cava grams" or CT scans) to confirm successful placement and positioning of the device within the vena cava.

30. Unfortunately, the G2 Filter also shares some of the defects of its ancestor. The G2 Filter's design causes it to be of insufficient integrity and strength to withstand normal placement within the human body. The global stressors of the respiratory and cardiac cycles of

the human body cause the G2 Filter to develop stress or "fatigue" fractures of the Nitinol surface of the device.

31. Also, like its predecessor, in addition to design defects, the G2 Filter suffers from manufacturing defects. These manufacturing defects primarily include the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2 Filter while *in vivo*. In particular, the G2 Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the G2 Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to fatigue failure.

32. The G2™ filter is advertised by defendants, C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc., to have "enhanced fracture resistance," "improved centering," and "increased migration resistance." Defendant Bard Peripheral Vascular's website[3] indicates that "data is on file" with respect to these product enhancements.

33. Despite the defendants' claims concerning the safety and efficacy of the G2 Filter, the FDA's "MAUDE" (Manufacturer and User Facility Device Experience) database includes several reports of the failure, fracture and migration of the G2 Filter.

34. Defendants represent the fracture rate of the G2 Filter to be 1.2%. Based upon a review of the data available in the public domain (including the F.D.A. MAUDE database statistics), this representation does not accurately reflect the true incidence of device fracture.

[3] *See* www.bardpv.com/_vascular/product.php?p=83 (last visited October 21, 2009).

35. A review of the MAUDE database from the years 2004 – 2008 reveals data to establish that the defendants' vena cava filters (including the G2 Filter) are responsible for a significant percentage of the reported adverse patient events involving vena cava filters. Specifically, the G2 Filter and the Recovery Filter combine account for and are responsible for the following event percentages:

a. 50 % of all "adverse events";

b. 64 % of all occurrences of migration of the device;

c. 69 % of all occurrences of vena cava wall perforation;

d. 70 % of all occurrences of filter fracture.

WHAT HAPPENS WHEN THE G2™ FILTER SYSTEM FAILS?

36. The failure (fracture and/or migration) of the G2 Filter System leads to a number of different, and potentially fatal, complications. These complications include, but are not limited to:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. Severe and persistent pain; and

e. Perforation of tissue, vessels and organs.

37. The person who experiences failure (fracture and/or migration) of the G2 Filter System typically experiences an acute onset of chest pain and shortness of breath. This typically results in the person presenting to an emergency room, hospital, and/or physician for evaluation.

THE CASE FOR MEDICAL MONITORING

38. In certain cases, medical monitoring is required to evaluate whether a G2 Filter (or portions of the G2 Filter) has experienced fracture, tilt or migration (collectively referred to herein as "device failure" or "failure"). In order to determine whether failure of the G2™ Filter System has occurred, imaging studies must be performed. Typically, these imaging studies will include un-enhanced computed tomography scan (CT Scan) so that the filter may be visualized. CT Scan imaging produces an image of the filter and is able to reveal whether the filter has fractured or migrated.

39. Those people requiring medical monitoring are recommended[4] to undergo regular and frequent imaging studies of the device or portions of the device at least once or twice annually. As long as the device, or portions of the device, remains within the body of the patient, the potential for future device failure exists. Consequently, these people require regular and frequent medical monitoring for the duration of time the device, or portions of the device, remain within their bodies.

40. Those eligible for medical monitoring of the G2 Filter or portions of the device need not have experienced past failure of the G2 Filter. For example, patients who have undergone implant of the G2 Filter frequently learn that the G2 Filter cannot be removed due to the fact that it has "grown into" tissue, but, that fracture, tilt or migration of the device may not

[4] Research studies performed in 2008 call for the need of regular and frequent medical monitoring for a patient who had the Recovery™ vena cava filter implanted in their body. This 2008 research study performed by Jeffrey Hull, M.D. recommends regular and frequent monitoring of patients in whom the Recovery Filter System remains implanted. (*Retrieval of the Recovery Filter after Arm Perforation, Fracture, and Migration to the Right Ventricle*, Hull *et. al.*, J. Vasc. Interv. Radiol. 2008; 19:1107-1111). Dr. Hull specifically recommends "imaging with un-enhanced abdominal CT to look for arm perforation, fracture, or migration to further evaluate the scope and risk posed by this [the Recovery™] filter." Given the fact that the Recovery and the G2 Filters share many characteristics – particularly manufacturing and design defects – the case for medical monitoring is likewise compellingly made for the G2 Filter.

yet have occurred. As a result of the inability to remove the G2 Filter, the device must remain permanently implanted in the patient, for the patient's lifetime. Although these patients may not yet have experienced device failure, they are at risk for future device failure and require regular and frequent monitoring to evaluate the integrity of the G2 Filter.

41. In addition to the aforementioned imagiing studies, endovascular intervention (typically cardiac catheterization) may also be used by medical professionals to diagnose or discover whether fractured portions of the G2™ Filter System have migrated to the heart or lungs. Furthermore, endovascular surgery may assess the nature and extent of the damage resulting from failure of the G2 Filter.

42. In those instances where devise fracture has occurred, and depending on the circumstances particular to the patient, a person may be required to undergo one or all of the following medical procedures:

a. CT Scanning or other imaging studies;

b. Cardiac catheterization;

c. Open heart surgery;

d. Removal of the G2™ Filter System from the vena cava.

PLAINTIFF'S DAMAGES AND THE FAILURE OF THE G2™ FILTER SYSTEM

43. The G2™ Filter System was placed in plaintiff's body on or about July 7, 2006. Plaintiff discovered that the G2 Filter System fractured on or about June 20, 2008. The fractured portions of the device migrated to her vital organs causing injury and damage. Plaintiff was caused to undergo medical treatment as a result of the failure of the G2 Filter System. Plaintiff has incurred significant medical expenses and has endured extreme pain and

suffering, loss of enjoyment of life, disability, and other losses, some of which are permanent in nature. As a result of the failure of the G2 Filter System, plaintiff has become impaired and her ability to earn wages has been diminished, and will remain so in the future. The G2 Filter System remains in plaintiff's body. Plaintiff is required to attend regularly scheduled physicians' visits and to undergo imaging studies to monitor her condition and to determine whether the G2 Filter System has experienced additional failure/fracture.

44. As a direct and proximate result of the conduct and defective product of the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, plaintiff LISA DAVIS has suffered permanent and continuing injury, loss of enjoyment of life, pain, suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries. Plaintiff's ability to carry on the affairs of her daily life has been impacted and diminished, and will continue to be diminished in the future.

45. As a direct and proximate result of the conduct and defective product of the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, the plaintiffs have incurred substantial medical expenses, and will continue to incur substantial medical expenses into the future.

THE NECESSITY FOR MEDICAL MONITORING

46. As a direct and proximate result of the conduct and defective product of the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, medical monitoring is necessary for Plaintiff LISA DAVIS. Medical monitoring includes:

a. Regularly scheduled CT scans or other appropriate imaging studies; and/or

b. Potential cardiac catheterization or other endovascular procedures to detect

the presence of migrated pieces of the G2™ Filter System; and/or

c. Physicians' visits and examinations.

THE DEFENDANTS' KNOWLEDGE OF THE FAILURE OF THE G2™ FILTER SYSTEM AND THE DANGERS ASSOCIATED WITH THE DEVICE

47. Upon information and belief, plaintiff alleges that as early as 2005, the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., were aware and had knowledge of the fact that the G2™ Filter System was defective and unreasonably dangerous and was causing injury and death to patients who had received the G2™ Filter System.

48. Data established that the failure rate of the G2™ Filter System was/is exceedingly higher than the rate the defendants have in the past, and currently continue to publish to the medical community, members of the public, and the FDA.

49. Upon information and belief, from the time the G2™ Filter System became available on the market, the defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., embarked on an aggressive campaign of "off label marketing" concerning the G2™ Filter System. This included representations made to physicians, healthcare professionals, and other members of the medical community that the G2™ Filter System was safe and effective for retrievable use prior to the FDA approving the G2™ Filter System for retrievable use in 2008.

50. The conduct of the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, constituted, willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of the plaintiff LISA DAVIS. The defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., had actual knowledge of the dangers presented by the G2™ Filter System, yet consciously failed to act reasonably to:

a. Inform or warn the plaintiff, her physicians, or the public at large of the dangers; and

b. Recall the G2™ Filter System from the market in a timely and safe fashion;

51. Despite having knowledge as early as 2005 of the unreasonably dangerous and defective nature of the product, the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., consciously disregarded the known risks and continued to actively market and offer for sale the G2™ Filter System.

52. The plaintiff further alleges that the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., acted in willful, wanton, gross and in total disregard for the health and safety of the user or consumer of its G2™ Filter System, including plaintiff LISA DAVIS, acted to serve her own interests and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

LIABILITY OF THE DEFENDANTS

COUNT ONE

(Negligence)

53. Plaintiff adopts and incorporate by reference all relevant preceding paragraphs from paragraphs 1-52 *supra* as paragraphs of this Count One.

54. At all times relevant to this cause of action, the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., were in the business of designing, developing, manufacturing,

marketing, and selling sophisticated medical devices, including the G2™ Filter System.

55. At all times relevant to this cause of action, the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., were under a duty to act reasonably to design, develop, manufacture, market, and sell a product that did not present a risk of harm or injury to the plaintiff LISA DAVIS and to those people receiving the G2™ Filter System.

56. At the time of manufacture and sale of the G2™ Filter System (2005 until present), the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., knew or should have known that the G2™ Filter System:

a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Was designed and manufactured so as to present a unreasonable risk of migration of the device and/or portions of the device; and/or

c. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

57. Despite the aforementioned duty on the part of the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., they committed one or more breaches of the duty of reasonable care and were negligent in:

a. Unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the G2™ Filter System, *to wit*, the incidence of failure of the G2™ Filter System;

b. Unreasonably and carelessly manufacturing a product, *to wit*, the G2™

Filter System, that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. Unreasonably and carelessly designing a product, *to wit*, the G2™ Filter System, that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

d. Unreasonably and carelessly designing a product, *to wit*, the G2™ Filter System, that presented a risk of harm to the plaintiff and others similarly situated in that it was prone to failure.

58. As a direct and a proximate result of the foregoing negligence by defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., the plaintiff LISA DAVIS suffered permanent and continuing injuries, pain and suffering, disability and impairment. LISA DAVIS has suffered emotional trauma, harm and injuries that will continue into the future. LISA DAVIS' ability to carry on the affairs of her daily life has been impacted and diminished, and will continue to be so diminished in the future. Furthermore, LISA DAVIS has lost earnings in the past and will continue to lose earnings in the future as a result of her impairment and disability in this regard.

59. The Plaintiff further alleges that in her actions and inactions, defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., acted in willful, wanton, gross and in total disregard for the health and safety of the user or consumer of its G2™ Filter System, including plaintiff LISA DAVIS, acted to serve her own interests and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.

COUNT TWO

(Breach of Implied Warranty)

60. Plaintiff adopts and incorporates by reference all relevant preceding paragraphs from paragraphs 1-59 *supra* as paragraphs of this Count Two.

61. Plaintiff, through LISA DAVIS' medical providers, purchased the G2 Filter System from defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.

62. At all times relevant to this cause of action, the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., were merchants of goods of the kind including endovascular medical devices and vena cava filters (like the G2™ Filter System).

63. At the time and place of sale, distribution, and supply of the defendants' G2™ Filter System to plaintiff, defendants impliedly warranted that the G2™ Filter System was safe, and impliedly warranted that the product was reasonably fit for its intended purpose and was of marketable quality. Contrary to the aforementioned implied warranties, the G2™ Filter System was not reasonably fit for its intended, anticipated, or reasonably foreseeable use.

64. At the time of the plaintiff's purchase of the G2™ Filter System from the defendants, it was not in a merchantable condition in that:

a. It was designed in such a manner (as set forth in more detail *supra*) so as to be prone to a statistically high incidence of fracture and/or migration;

b. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy; and

c. It was manufactured in such a manner so that the exterior surface of the G2™ Filter System was inadequately, improperly and inappropriately prepared and/or finished causing the device to weaken and fail.

65. Additionally, implied warranties were breached in that:

a The defendants failed to provide the warning or instruction and/or an adequate warning or instruction which a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that said G2™ Filter System would cause harm;

b. The defendants manufactured and/or sold the G2™ Filter System that did not conform to representations made by the defendants, when it left the defendants' control;

c. The defendants manufactured and/or sold the G2™ Filter System that was more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the G2™ Filter System's design or formulation exceeded the benefits associated with that design or formulation. These defects existed at the time the product left the defendants' control; and

d. The defendants manufactured and/or sold the G2™ Filter System that deviated in a material way from the design specifications, formulas, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards, and these defects existed at the time the product left the defendants' control.

66. Furthermore, defendants' marketing of the G2™ Filter System was false and/or misleading.

67. Plaintiff, through her attending physicians, and through the Henry Ford Bi-County Hpspital Radiology Department, relied on these representations in determining which IVC filter to use in the implantation in plaintiff.

68. Defendants' G2™ Filter System was unfit and unsafe for use by users as it posed an unreasonable and extreme risk of injury to persons using said product, and accordingly defendants breached the implied warranties associated with the product.

69. The foregoing warranty breaches were a substantial factor in causing plaintiff's injuries and damages as alleged.

70. As a direct and a proximate result of the foregoing condition of the product of defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., plaintiff, LISA DAVIS suffered permanent and continuing injuries, pain and suffering, disability and impairment. LISA DAVIS has suffered emotional trauma, harm and injuries that will continue into the future. LISA DAVIS' ability to carry on the affairs of her daily life has been impacted and diminished, and will continue to be so diminished in the future. Furthermore, LISA DAVIS has lost earnings in the past and will continue to lose earnings in the future as a result of her impairment and disability in this regard.

71. The Plaintiff further alleges that the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., acted in willful, wanton, gross and in total disregard for the health and safety of the user or consumer of its G2™ Filter System, including plaintiff LISA DAVIS, acted to serve their own interests and having reason to know and consciously disregarding the

substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

COUNT THREE

(Negligent Misrepresentations concerning the G2™ Filter System)

72. Plaintiff adopts and incorporate by reference all relevant preceding paragraphs from paragraphs 1-71 *supra* as paragraphs of this Count Three.

73. At all times relevant to this cause, and as detailed *supra*, the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., negligently provided plaintiff, the public at large, the medical community, and/or the FDA with false or incorrect information, or omitted or failed to disclose material information concerning the G2™ Filter System, including, but not limited to, misrepresentations relating to the following subject areas:

a. The safety of the G2™ Filter System;

b. The efficacy of the G2™ Filter System;

c. The rate of failure of the G2™ Filter System; and

d. The approved uses of the G2™ Filter System.

74. Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., intended that plaintiff, the public at large, the medical community, and/or the FDA rely on information they provided and defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., provided it for that purposes.

75. Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., failed to exercise reasonable care or competence in obtaining or communicating the information to plaintiffs, the public at large, the medical community, and/or the FDA.

76. The plaintiff, the plaintiff's healthcare providers and the medical community at large relied on the misrepresentations of the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., in this regard, their reliance was justified, and as a direct and proximate result, the plaintiffs were damaged as aforesaid.

77. The plaintiff further alleges that the defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., acted in willful, wanton, gross and in total disregard for the health and safety of the user or consumer of its G2™ Filter System, including plaintiff LISA DAVIS, acted to serve their own interests and having reason to know and consciously disregarding the substantial risk that as a result of their negligent misrepresentations may results in their product killing or significantly harming patients, or significantly injuring the rights of others, consciously pursued a course of making misrepresentations knowing that such misrepresentations created a substantial risk of significant harm to other persons.

PRAYER FOR RELIEF

WHEREFORE, the plaintiff prays this court will award actual damages in excess of Seventy-five Thousand Dollars ($75,000.00) against the defendants, joint and severally, by reason of said negligence, gross negligence, intentional conduct, and other breaches of duty as alleged herein proximately caused by the fault of the defendants, lost wages, and special damages, in an amount to be determined by the trier of fact plus costs of this action, and for such other further relief to which the plaintiff may be justly entitled, at law and/or in equity.

PLAINTIFF REQUESTS TRIAL BY JURY ON ALL ISSUES SO TRIABLE.

LISA DAVIS, Plaintiff

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